AUG 2 3 2001

Premarket Notification
510(k) Summary

[As required by 21CFR 807.92(a)]

Trade Name: ISI-2500
Common Name: C-arm
Classification Name: Mobile X-ray System

I certify that, in my capacity as President of Imaging Services, Inc., The ISI-2500 C-arm is equivalent to the OEC Medical Systems 9600 mobile c-arm. Mechanically and electrically the ISI-2500 C-arm is as safe and effective as this c-arm. The key difference between the OEC Medical Systems 9600 c-arm and the ISI-2500 is the imaging chain or CCD Camera and Camera Control Unit. The intended use for the ISI-2500 is the same as this and any other c-arm is use today.

This c-arm is made by Medison, Ltd., in Korea under the model number MCA-901. Though new to the U.S. this system has and is being sold in Korea, Asia, Central and South America.

Imaging Services, Inc. tests the system to comply with all Federal, State and BRH standards. This device complies with all electrical standards including but not limited to UL 2601-1, IEC 60601-1-3, IEC 60601-2-7 and IEC 60601-2-28.

This product provides a high end, low cost c-arm to customers who cannot afford the rising costs of medical equipment, while maintaining superior image quality as with a more expensive product.

Imaging Services, Inc.
8210 Lankershim Blvd #1
North Hollywood, CA 91605
(800) 900-9729
(818) 504-9185 Fax

Dean N. Janes, President / CEO

K010772

(Premarket Notification [510(k)] number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2001

Mr. Dean Janes
President/CEO
Imaging Services, Inc.
8210 Lankershim Blvd. # 1
N. HOLLYWOOD CA 91605

Re: K010772
ISI-2500 CCD C-arm (C-arm mobile x-ray system)
Dated: May 25, 2001
Received: June 12, 2001
Regulatory Class: II
21 CFR 892.1650/Procode: 90JAA
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. Janes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Applicant: Imaging Services, Inc.

510(k) No. (if known): K010772

Device Name: ISI-2500

Indications For Use: The ISI-2500 Mobile C-arm is designed to provide fluoroscopic imaging of the patient during diagnostic and surgical procedures. Clinical applications include but are not limited to general surgery, gastro-intestinal, urologic, orthopedic, neurologic, vascular and emergency room procedures. This system may be used for other imaging applications at the physicians discretion.

(Please Do Not write below this line – Continue on another page if needed)

Concurrence of CDRH Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010772

Prescription Use ✓ OR Over-the-Counter _____
(Per 21 CFR 801.109)